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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/509,447

09/28/2004

Hiroki Hibino

18259

7448

23389

7590

09/05/2007

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EXAMINER

EDWARDS, LYDIA E

ART UNIT

PAPER NUMBER

1709

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DELIVERY MODE

09/05/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/509,447

Applicant(s)

HIBINO ET AL.

Examiner

Lydia Edwards

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/28/2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☒ Claim(s) 15-18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date See Continuation Sheet.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :9/28/2004, 12/30/2004, 8/04/2006, 5/21/2007.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :9/28/2004, 12/30/2004, 8/04/2006, 5/21/2007.

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities: reference is made to the claims on pages 4-6 and 9-14.

Appropriate correction is required.

Abstract

The abstract of the disclosure is objected to because there is more than one paragraph. Correction is required. See MPEP § 608.01(b).

Claim Objections

Claims 15-18 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend on another multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 15-18 have not been further treated on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 12-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Regarding Claim 3, the examiner is unclear about what is meant by "a rewriting unit that rewrites the previously stored identification information to other recently input identification information in the case any of the identification information input from the input unit is already stored in the memory unit."

Regarding claims 12-14, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Claus et al. (CA 2303243).

Regarding Claim 1, Claus et al. ('243) discloses a system that carries in collected cells and contains them in an incoming transport container to which is attached unique identification information, transfers the transported cells to and cultures them in an intermediate container to which is attached unique identification information, and carries out the cultured cells by transferring them to an outgoing transport container to which is attached unique identification information; said system comprising an input unit that inputs identification information attached to the containers before and after transfer whenever cells are transferred to a different container, and a memory unit that stores in memory identification information input from the input unit in mutual correlation (paragraphs 35-44).

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The reference does not specifically state an input unit however; the examiner deems figure 1 elements 1-2, 4 and 5 to be analogous to an input unit as described in paragraph 92.

Regarding Claim 2, Claus et al. ('243) discloses a system wherein in the case any of the identification information input from the input unit is already stored in memory, the memory unit stores other recently input identification information by adding to the existing identification information (paragraphs 40-44).

The reference does not specifically state an input unit however; the examiner deems figure 1 elements 1-2, 4 and 5 to be analogous to an input unit as described in paragraph 92.

Regarding Claim 3, Claus et al. ('243) discloses system further comprising a unit that is capable of rewriting previously stored identification information already stored in the memory unit (paragraphs 85 and 92).

The examiner is interpreting the method against falsification as being analogous to rewriting previously stored identification information.

Regarding Claim 4, Claus et al. ('243) disclose a system wherein the identification information includes information relating to the steps in which each container is used (paragraph 45).

Regarding Claim 6, Claus et al. ('243) discloses a system further comprising a collating unit that collates cultured cells according to whether or not their correlation agrees with a correlation stored in the memory unit in the case the outgoing transport container identification information and the incoming transport container identification information are input as judgment information for collating cultured cells (paragraphs 45-54).

Regarding Claim 7, Claus et al. ('243) discloses a system, further comprising, in the case identification information of the outgoing transport container has been input as judgment information for collating cultured cells, a reading unit that reads identification information

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correlated with identification information of the outgoing transport container from the memory unit, and an output unit that outputs the read identification information, are additionally provided (paragraphs 35-57, 61 and 92).

Regarding Claim 8, Claus et al. ('243) discloses a device for collating incoming cultured cells with patients for use in a cell culturing system provided with a memory unit, which together with carrying in collected cells by containing them in an incoming transport container to which is attached unique identification information, culturing the incoming cells by transferring to an intermediate container to which is attached unique identification information, and carrying out the cultured cells by transferring them to an outgoing transport container to which is attached unique identification information, correlates and stores in memory the identification information attached to the containers before and after transfer when ever the cells are transferred to a different container; said device comprising, an input unit that inputs incoming transport container identification information and outgoing transport container identification information as targets for collation, a judgment unit that judges whether the correlation of identification information input from the input unit agrees with correlation information stored in the memory unit, and an output unit that outputs the judgment result (paragraphs 35-57, and 61).

The reference does not specifically state an input unit however; the examiner deems figure 1 elements 1-2, 4 and 5 to be analogous to an input unit as described in paragraph 92.

Regarding Claim 9, Claus et al. ('243) discloses a device for collating incoming cultured cells with patients for use in a cell culturing system provided with a memory unit, which together with carrying in collected cells by containing them in an incoming transport container to which is attached unique identification information, culturing the incoming cells by transferring to an intermediate container to which is attached unique identification information, and carrying out the cultured cells by transferring them to an outgoing transport container to which is attached unique identification information, correlates and stores in memory the identification information attached to the containers before and after transfer when ever the cells are transferred to a

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different container; said device comprising, an input unit that inputs identification information of the incoming transport container or outgoing transport container as judgment information for collating cultured cells, a reading device that reads identification information from the memory unit that is correlated with the identification information input from the input unit, and an output unit that outputs the read identification information (paragraphs 35-57, 61, and 85).

The reference does not specifically state an input unit however; the examiner deems figure 1 elements 1-2, 4 and 5 to be analogous to an input unit as described in paragraph 92.

Regarding Claim 10, Claus et al. ('243) discloses a device that cultures cells by transferring the cells to culture containers to which are attached unique identification information according to the cell culturing process; comprising, an input unit that inputs identification information attached to culture containers before and after transfer whenever cells are transferred to a different culture container, and a memory unit that stores identification information input from the input unit in mutual correlation (paragraphs 35-57, 61, 63, 73, and 85).

The reference does not specifically state an input unit however; the examiner deems figure 1 elements 1-2, 4 and 5 to be analogous to an input unit as described in paragraph 92.

Regarding Claim 11, Claus et al. ('243) discloses a device further comprising a large number of culturing chambers to which are attached unique identification information; wherein, the input unit inputs identification information attached to a culture container and culturing chamber each time a culture container enters and leaves a culturing chamber, and the memory unit stores the identification information input from the input unit in mutual correlation (paragraphs 35-57, 61, 63, 73, and 85).

The reference does not specifically state an input unit however; the examiner deems figure 1 elements 1-2, 4 and 5 to be analogous to an input unit as described in paragraph 92.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Claus et al. (CA 2303243) in view of Lerch et al (WO 97/19754).

Regarding Claim 5, Claus et al. ('243) does not teach a system, wherein information on the hospital that is the origin of the incoming transport container is added to the incoming transport container.

Lerch et al. ('754) discloses a system, wherein information on the hospital that is the origin of the incoming transport container is added to the incoming transport container (page 8).

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It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Claus et al. to include hospital information on the incoming transport container as taught by Lerch et al. to provide automatic sample identification.

Regarding Claim 12, Claus et al. ('243) does not teach a sensor.

Lerch et al. ('754) discloses a sensor, in each culturing chamber, that detects internal culturing chamber information (page 5).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Claus et al. to include a sensor that detects internal culturing chamber information as taught by Lerch et al. to provide adequate feedback on the cell culturing process.

Claims 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Claus et al. (CA 2303243) and Lerch et al (WO 97/19754) as applied to claim 12 above, and further in view of Pfaller (US 6329195).

Regarding Claim 13, the primary references do not disclose a medium replacement unit that replaces medium that has accumulated in a culture container.

Pfaller ('195) discloses a medium replacement unit that replaces medium that has accumulated in a culture container (Col 2, lines 47-58).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Claus et al. or Lerch et al. with a medium replacement unit that replaces medium that has accumulated in a culture container as taught by Pfaller to provide adequate sample feedback during the cell culturing process.

Regarding Claim 14, the primary references do not specifically disclose medium information detection unit that detects medium.

Pfaller ('195) discloses a medium replacement unit that replaces medium that has accumulated in a culture container (Col 2, lines 47-58).

Lerch et al. ('754) discloses a sensor, in each culturing chamber, that detects internal culturing chamber information (page 5).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Claus et al. with a medium replacement unit that replaces medium that has accumulated in a culture container as taught by Pfaller to provide adequate sample feedback during the cell culturing process in addition to a sensor as taught by Lerch et al. to provide a signal/indicator for the sample medium information.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lydia Edwards whose telephone number is (571) 270-3242. The examiner can normally be reached on Mon-Fri 8-5 (Alternate Fri).

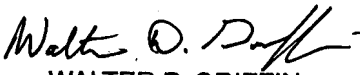
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on (571) 272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lydia Edwards
Examiner
Art Unit 1709

LE


WALTER D. GRIFFIN
SUPERVISORY PATENT EXAMINER